GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:18
ANSWERED ON:01.12.2004
DISCONTINUING USE OF PAINKILLER ROFECOXIB
Chandrappan Shri C.K.;Sen Smt. Minati

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether serious steps have not been undertaken by the Government to discontinue the use of the popular painkiller 'ROFECOXIB' even after scientists have raised questions about its safety;

(b) if so, the reasons therefore;

(c) whether the authoritative medical journal "LANCET" in its latest issue has revealed the side-effects of using the said drug;

(d) if so, the details thereof;

(e) whether the said drug has already been withdrawn from several foreign markets;

(f) if so, the names of such countries; and

(g) the measures proposed to be taken by the Government to withdraw this drug from the Indian markets urgently?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(g): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 18 FOR 1ST DECEMBER, 2004

As soon as the report about voluntary withdrawal of Rofecoxib by the innovator firm M/s Merck, USA became known on 30th September, 2004, immediate measures were initiated to review the safety profile of the drug in India where this drug is being manufactured and marketed by a number of firms.

An emergency meeting of the National Pharmacovigilance Advisory Committee was convened on 11th October, 2004, to consider the situation arising out of the voluntary withdrawal of the said drug by the innovator firm M/s Merck, USA. After examining the available information including the article in the Journal `LANCET`, it was decided by the Committee to discontinue the use of Rofecoxib in the country. A press note to this effect was also issued on 12th October, 2004. The prohibition to manufacture and sell the drug across the country has to be done through Notification under Section 26 A of the Drugs and Cosmetics Act, 1945. This Notification is being issued accordingly.

There is no information available about the withdrawal of the drug by the regulatory agency of any country prior to its voluntary withdrawal by M/s Merck, USA.